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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,083	02/04/2004	Daniel J. Cua	DX06023 US 01	3286

28008 7590 10/21/2005

DNAX RESEARCH, INC.  
LEGAL DEPARTMENT  
901 CALIFORNIA AVENUE  
PALO ALTO, CA 94304

EXAMINER
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JALLA, SANJOO

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,083

Applicant(s)

CUA ET AL.

Examiner

Sanjoo Shree Jalla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Detailed Action

1. The examiner of this application in the PTO has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Sanjoo Jalla, Group Art Unit 1644, Technology Center 1600.
2. Claims 1-20 are cancelled. Claims 21-28 (new) are under consideration in the instant application. Election was made without traverse in Remarks/argument sheet on 08/08/2005. Further, during a telephone conversation with Sheela Mohan Peterson on 09/16/05, a provisional election was made without traverse to prosecute the invention of claim 21-28(new) using only an antigen binding fragment of an antibody as an antagonist of IL-23.
3. Applicant should restrict the title to the claimed invention. The title reads " Uses of mammalian cytokine; related reagents" whereas the claimed invention comprises a method of treating an IL-23 mediated disorder. A new title is required that is clearly indicative of the invention to which the claims are directed.
4. The abstract of the disclosure is objected to as not accurately describing the claimed invention. Correction is required. See MPEP § 608.01(b).
5. Applicant's submission of Search Reports on the IDS (11/01/2004) is acknowledged, however reference CD is crossed out as it is a duplicate reference and reference CG is crossed out as it was not submitted.
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that forms the basis for the rejection under this section made in this office action:

*A person shall be entitled to a patent unless-*

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United

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States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004/042009.

WO 2004/042009 teaches a method of the treatment of an inflammatory disease comprising administering to the subject an effective amount of an antagonist of interleukin-23 (IL-23) wherein the antagonist is an antibody or a fragment of an antibody (see page 2, lines 12-15 and 25-26). WO 2004/042009 further teaches that the IL-23 antagonist to be a monoclonal antibody (which includes humanized antibodies or fragments thereof, such as Fv, Fab, F (ab')<sub>2</sub>) or a polyclonal antibody (see page 8, lines 10-13 and 19-21). Further, WO 2004/042009 teaches the inflammatory disease to be an inflammatory bowel disease (IBD) (a well known gastrointestinal disorder) such as Crohn's disease and ulcerative colitis (see page 9, lines 11 and 14-15).

Further, chronic inflammatory bowel diseases like Crohn's disease and ulcerative colitis inherently encompasses histological changes (as claimed in claim 27). For example, Crohn's disease is characterized by abnormal mucosal architecture and lamina propria cellularity, neutrophil infiltration and epithelial cell abnormality as evidenced by Winther et.al. (Drugs Today, 1998; 34: 935).

Further, claim 28 is an additional characterization of the properties of an antagonist of IL-23.

The reference clearly anticipates the invention.


7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sanjoo Jalla, Ph.D.  
Patent Examiner  
Technology Center 1600

  
10/14/08  
G.R. EWOLDT, PH.D.  
PRIMARY EXAMINER